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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/777,802	02/12/2004	Sheng-Ping (Samuel) Zhong	03-235	5369

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EXAMINER	
AHMED, HASAN SYED	
ART UNIT	PAPER NUMBER
1615	

MAIL DATE	DELIVERY MODE
11/23/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/777,802	ZHONG, SHENG-PING (SAMUEL)	
	Examiner	Art Unit	
	HASAN S. AHMED	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 July 2010*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3,10-17 and 19-28* is/are pending in the application.

4a) Of the above claim(s) *10-16,20,24 and 26* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3,17,19,21-23,25,27, and 28* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

- After further consideration, finality of the previous Office action is hereby withdrawn.
- Applicants' arguments filed on 23 July 2010 have been considered but are moot in view of the new grounds of rejection.
- The claim objection presented in the previous Office action is withdrawn in view of the claim amendment filed on 1 June 2010.

* * * * *

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1, 3, 17, 19, 21-23, 25, 27, and 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 2003/026532 ("Weber") (currently of-record) in view of U.S. Patent No. 6,743,463 ("Weber II") (currently of-record), further in view of U.S. 5,998,528 ("Tsipursky").

Weber teaches a medical article comprising a release region (*see* page 2, lines 22-28), further comprising:

- the implantable or insertable medical device of instant claim 1 (*see* page 20, lines 16-21);
- the polymeric carrier comprising a first hydrophobic polymer (e.g. polyolefin) of instant claim 1 (*see* page 8, lines 5-15);

- the drug loaded nanoparticles dispersed within the polymeric carrier of instant claim 1 (*see* page 5, line 18; page 10, line 27; page 11, lines 14-16);
- the layered silicate material (phyllosilicate) of instant claim 1 (*see* page 9, line 4);
- the hydrophilic therapeutic agent of instant claim 1 (*see* page 11, line 17 – page 12, line 6; *e.g.* acetylsalicylic acid);
- the hydrophobic first polymer of instant claim 1 (*see* page 8, lines 5-15; *e.g.* polyolefin block copolymer);
- the disposal over at least a portion of the medical article substrate of instant claim 17 (*see* page 10, lines 24-26; figure 1);
- the coronary or peripheral vasculature implantable or insertable medical device of instant claim 19 (*see* page 20, lines 16-21);
- the catheter of instant claim 21 (*see* page 20, line 19);
- the antithrombotic agent of instant claim 22 (*see* page 11, line 18);
- the smectite silicate material of instant claim 23 (*see* page 9, line 4);
- the method of instant claim 25 (*see* page 6, lines 3-15);
- the overlapping cross-sectional length of instant claim 27 (*see* page 8, line 20); and
- the olefin polymer of instant claim 28 (*see* page 8, lines 5-15).

Regarding the hydrophilic second polymer of claim 1 (*see* page 8, lines 5-15; *e.g.* polyacrylics); it is noted that Weber teaches that the matrix material can be a polymer blend (*see* page 8, line 4) – as such, Weber envisions using a combination of any of the

matrix materials listed in the subsequent paragraph (*see* page 8, lines 5-15) which includes a hydrophobic polymer such as a polyolefin block copolymer and a hydrophilic polymer such as a polyacrylic polymer).

Weber explains that the disclosed device is beneficial because it provides targeted and controlled delivery of therapeutic agents to a desired treatment site (*see* page 11, lines 5-6).

Weber does not disclose the spacing between adjacent layers within the silicate particles recited in instant claim 27. However, Weber teaches use of the same silicate as the instant application, *i.e.*, smectite silicate (*see* page 9, line 4), and spacing between adjacent layers is an inherent feature of the silicate.

Weber differs from the instant application in that it does not teach halofuginone as a therapeutic agent.

Weber II teaches an insertable medical device, such as a stent (*see* col. 2, line 27). The device may be coated with a hydrophobic polymer (reading on the polymeric carrier comprising a hydrophobic first polymer of instant claim 1) (see col. 9, lines 24-60). Disclosed hydrophobic polymers include polyurethanes, polysiloxanes, styrene-isobutylene copolymers, polyolefins, polyisobutylenes, ethylene-alphaolefins, acrylic polymers, polyamides, polycaprolactones, etc. (see col. 9, lines 31-60) (reading on claim 28). The coating formulation may further comprise a nanocomposite comprising nanoclay particles (*see* col. 10, line 19) and with a biologically active material (*see* col. 10, lines 51-52) such as halofuginone (*see* col. 12, line 7) (reading on claim 3) and a

hydrophilic polymer, such as albumin, carbohydrate, or polysaccharide (see col. 13, line 2) (reading on the hydrophilic second polymer of claim 1).

Weber and Webber II do not explicitly disclose the placement of the therapeutic agent in the spaces between adjacent layers of the silicate material of each silicate particle to form a depot. However, the placement of a hydrophilic therapeutic agent and a hydrophilic polymer in the spaces between the adjacent layers of the silicate material is a property of interaction between the silicate and the hydrophilic therapeutic agent and polymer, as explained by Tsipursky (see col. 5, lines 9-19):

> It is theorized that polar moieties from the intercalant molecules, which complex to the interlayer cations in the interlayer spaces between the platelets of the layered material, also complex with the added cations, and the complexed metal salt-derived cations carry their dissociated anions along with the cations, in the interlayer space, in order to maintain charge neutrality within the interlayer spaces of the layered material. It is theorized that such double intercalant complexing (intercalant with interlayer cations and with cations from the added metal salt compound) occurs on adjacent, opposed platelet surfaces, resulting in repulsion between closely spaced dissociated anions carried by the added cations, resulting in increased basal spacing and more complete exfoliation using less intercalant.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to disclose an implantable or insertable medical device comprising a polymeric carrier comprising a hydrophobic first polymer and drug loaded nanoparticles dispersed within said polymeric carrier, said drug loaded nanoparticles comprising a layered silicate material and a hydrophilic first therapeutic agent (such as halofuginone) and hydrophilic second polymer, as taught by Weber in view of Webber II further in view of Tsipursky. One of ordinary skill in the art at the time the invention was made would have been motivated to make such a composition because it provides

targeted and controlled delivery of therapeutic agents to a desired treatment site, as explained by Weber (*see* above).

*

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to HASAN S. AHMED whose telephone number is (571)272-4792. The examiner can normally be reached on 9am - 5:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert A. Wax can be reached on (571)272-0623. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/H. S. A./
Examiner, Art Unit 1615

/Robert A. Wax/
Supervisory Patent Examiner, Art Unit 1615